UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AZURITY PHARMACEUTICALS, INC., **Plaintiff,** **v.** **EDGE PHARMA, LLC f/k/a, EDGE PHARMACY SERVICES, LLC,** **Defendant.**	**Civil Action No. _____**

COMPLAINT

Plaintiff Azurity Pharmaceuticals, Inc. ("Plaintiff" or "Azurity") f/k/a CutisPharma, Inc. brings this action against Defendant Edge Pharma, LLC f/k/a Edge Pharmacy Services, LLC ("Defendant" or "Edge") and alleges the following:

SUMMARY OF THE ACTION

1. Azurity brings this action to seek relief and to stop Edge from unlawfully manufacturing and selling unapproved new drugs under the false guise that it is engaged in lawful "compounding" and from engaging in false and misleading advertising and promotion of its unapproved new drugs.

2. Edge claims to be an "outsourcing facility" exempt from federal and state laws requiring drug manufacturers to demonstrate the safety and effectiveness of its drugs prior to marketing them. Edge, however, is in violation of necessary conditions that would allow it to take advantage of the "outsourcing facility" exemption.

3. Specifically, Edge produces an oral vancomycin hydrochloride solution that is identical or nearly identical to Azurity's FIRVANQ® (vancomycin hydrochloride, for oral solution). Additionally, Edge produces its oral vancomycin hydrochloride solution using bulk

drug substances, in violation of the conditions for an "outsourcing facility." For ease of reference, "vancomycin hydrochloride" will hereafter be referred to as "vancomycin."

4. Moreover, Edge markets and promotes its vancomycin oral solution and other drug products by highlighting that it meets the requirements for an "outsourcing facility." Defendant purports to avoid drug-approval requirements by falsely advertising its products as lawfully compounded, when in fact Defendant's products are not. Section 43(a) of the Lanham Act prohibits those engaged in commerce from precisely this type of unfair competition and false advertising by creating a cause of action for those like Azurity who are harmed by it. 15 U.S.C. § 1125(a)(1).

5. Worse still, Edge is engaging in unlawful compounding, placing at risk the health and safety of every patient who receives one of its drugs by exposing them to drugs that have not been approved as safe or effective. Indeed, the FDA in 2015 and again in 2018 inspected Edge's facility and found that it was manufacturing products in unsanitary conditions.

6. Azurity brings this action pursuant to Section 43(a) of the Lanham Act and Chapter 93A of the Massachusetts General Laws (Massachusetts' unfair trade practices law) to stop Edge from misleading health care providers about its business, and from unlawfully manufacturing, marketing, selling, and distributing unapproved new drugs, including vancomycin oral solution.

7. Azurity seeks relief in the form of a declaration that Edge is unlawfully producing and selling vancomycin and is misleading health care providers about the lawfulness of its practices and is therefore in violation of the Lanham Act and Massachusetts's unfair trade practices laws.

8. Azurity also seeks a preliminary and permanent injunction prohibiting Defendant from further manufacturing, marketing, and selling vancomycin and from misleading doctors and patients, and further seeks actual damages it has incurred because of Edge's production and sale of vancomycin oral solution, plus attorney's fees and costs.

PARTIES

9. Azurity is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Woburn, Massachusetts.

10. Azurity is a specialty pharmaceutical company that makes safe, high-quality treatments for patients who require formulations of drugs other than what is commonly commercially available.

11. Azurity has a growing portfolio of FDA-approved drugs, eliminating the need for compounding and giving patients an easy-to-consume medication that meets the FDA's safety and effectiveness standards. Among the FDA-approved drugs that Azurity markets in this District and throughout the United States is FIRVANQ® (vancomycin hydrochloride, for oral solution).

12. Upon information and belief, Edge is a limited liability corporation organized and existing under the laws of Delaware, with its principal place of business located at 856 Hercules Drive in Colchester, Vermont.

13. Upon information and belief, William Chatoff is the owner, managing director, and Chief Executive Officer of Edge, and resides in Vermont.

14. Edge markets, sells, and distributes its products throughout Massachusetts and nationwide.

JURISDICTION AND VENUE

15. This Court's subject matter jurisdiction is based upon federal question jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff alleges a violation of the Lanham Act, 15 U.S.C. § 1125(a)(1), and diversity jurisdiction pursuant to 28 U.S.C. § 1332(a)(1) because the parties are citizens of different states and the amount in controversy exceeds $75,000. Additionally, the Court has supplemental jurisdiction over the state law claims asserted herein pursuant to 28 U.S.C. § 1367.

16. The Court has personal jurisdiction over Edge because it transacts business within the Commonwealth of Massachusetts.

17. Venue is proper under 28 U.S.C. § 1391(b)(2) because Edge markets, sells, and distributes pharmaceutical drugs in this District, and a substantial part of the events or omissions giving rise to the claim occurred in this District.

FACTUAL BACKGROUND

I. Section 503B of the FDCA.

18. Prior to marketing any drug, the Federal Food, Drug, and Cosmetic Act (the "FDCA") requires pre-approval by the FDA of the safety and effectiveness of all drugs.

19. Compounded drugs, or drugs which are produced through the act of "combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug," 21 U.S.C. § 353b(d)(1), are excluded from the FDCA's pre-approval requirements where local pharmacists compound drugs in small quantities to fill the needs of individual patients with valid prescriptions. *See generally*, 21 U.S.C. § 353a (Section 503A of the FDCA). In other words, compounded drugs do not undergo the pre-market review for safety and effectiveness.

20. In 2013, after a compounding facility in Massachusetts produced contaminated injections that resulted in a meningitis outbreak killing more than 60 people and infecting hundreds, Congress passed the Drug Quality and Security Act, which added section 503B to the FDCA. Section 503B created a new category of drug manufacturer called an "outsourcing facility." *See* 21 U.S.C. § 353a.

21. Outsourcing facilities are permitted to sell quantities of compounded drugs directly to hospitals and health care professionals without obtaining individual patient prescriptions, and without pre-market approval from the FDA, as long as the facility satisfies certain requirements set forth in section 503B, 21 U.S.C. § 353b.

22. One such requirement concerns an outsourcing facility's use of "bulk drug substances," or a drug's active ingredient. An outsourcing facility may only compound with a "bulk drug substance" if that substance appears on an FDA list "identifying bulk drug substances for which there is a clinical need," 21 U.S.C. § 353b(a)(2)(A)(i), or if "the drug compounded from such bulk drug substance appears on the drug shortage list." *Id.* § 353b(a)(2)(A)(ii). Upon information and belief, Edge does not comply with either of these requirements with respect to vancomycin, as the bulk drug substance it uses to produce vancomycin does not appear on the specified FDA lists.

23. Another requirement of section 503B is that the drug compounded by the outsourcing facility "is not essentially a copy of one or more approved drugs." 21 U.S.C. § 353b(a)(5). A drug qualifies as "essentially a copy of an approved drug" if, for example, it is "identical or nearly identical to an approved drug." *Id.* § 353b(d)(2)(A). Such drugs may be produced under section 503B only if the approved drug is on the FDA's shortage list. *Id.* Upon

information and belief, Edge does not comply with this requirement, as the vancomycin it sells is essentially a copy of an FDA-approved drug.

24. The restriction on compounding drugs that are essentially copies of approved products ensures that patients are not unnecessarily exposed to un-tested drug products when they could use an approved product. FDA, *Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, (Jan. 2018) ("2018 Essential Copies Guidance") at 4.[1]

25. In addition to mitigating public health risk, the prohibition on producing copies of approved drugs "protects the integrity and effectiveness of the new drug and abbreviated new drug approval process." *Id.*

26. Section 503B specifies that a drug produced in a 503B facility is eligible for the exemption from the drug-approval requirement only if "the compounding of drugs occurs only in accordance with this section" in such facility. 21 U.S.C. § 353b(a)(11). As a result, Edge's violations of section 503B's requirements at its purported 503B facility deprive all of its products produced at that facility of the exemption from the drug-approval requirement, unless those drugs are on the specified FDA lists.

II. Edge's Failure to Comply with Section 503B.

27. Upon information and belief, Edge is a compounding facility that produces a wide variety of sterile and non-sterile compounded medications for hospitals, surgery centers, and clinics.

28. Edge formulates, markets, and distributes drugs as alternatives to FDA-approved drugs nationwide. Edge is licensed to sell in all U.S. states except Alabama and Virginia.

[1] FDA, 2018 Essential Copies Guidance, https://www.fda.gov/media/98964/download.

29. Edge formulates dozens of drugs including antimicrobials across a range of therapeutic specialties, including dermatology, ophthalmology, urology, pulmonology, anesthesiology, allergy, ENT, and gynecology.

30. Edge specializes in drugs that are typically back-ordered, discontinued, or otherwise available in low volumes, and bulk production of high volume medications regularly used in hospitals.

31. Edge registered with the FDA as a purported outsourcing facility under section 503B on January 21, 2014. Defendant, however, violates multiple conditions in section 503B.

32. According to its website, Edge produces and markets an oral vancomycin solution that competes directly with Azurity's FIRVANQ®. EDGEpharma, Vancomycin Oral Solution, https://edgepharma.com/products/oral-solutions/oral-vancomycin-solution/ (last visited February 11, 2020).

33. On January 26, 2018, a New Drug Application (NDA) for FIRVANQ® (vancomycin hydrochloride, for oral solution) was approved by the FDA for RxM™ Therapeutics, LLC (a Wholly-Owned Subsidiary of CutisPharma, Inc.).

34. Subsequently, in early 2018, Azurity launched FIRVANQ®, an FDA-approved vancomycin hydrochloride for oral solution indicated for treatment of *Clostridium difficile*-associated diarrhea and Enterocolitis caused by *Staphylococcus aureus,* including methicillin-resistant strains.

35. Azurity has invested significant time and resources to research, develop, and test FIRVANQ® in order to ensure that it is safe and effective, which enabled it to obtain regulatory approval from the FDA to market the drug.

36. Between April 2, 2018 and September 11, 2019, FIRVANQ® was the only commercially available FDA-approved vancomycin hydrochloride for oral solution.

37. Since September 11, 2019, FIRVANQ® is one of two commercially available FDA-approved vancomycin hydrochlorides for oral solution.

38. FIRVANQ® comes in 25 mg/mL or 50 mg/mL kits, and each kit contains a bottle of vancomycin hydrochloride USP powder for oral solution and a bottle of grape-flavored diluent for simple reconstitution.

39. The grape-flavored diluent is poured into the bottle containing the vancomycin hydrochloride USP powder. The powder dissolves into the liquid for oral administration.

40. Vancomycin hydrochloride is the active ingredient in FIRVANQ®.

41. Edge markets and produces a cherry-flavored, liquid, oral dose solution of vancomycin available in 125 mg, 250 mg, and 500 mg doses. EDGEpharma, Vancomycin Oral Solution, *supra* ¶ 32.

42. FIRVANQ® does not appear on the FDA's drug shortage list. *See* Current and Resolved Drug Shortages and Discontinuations Reported to FDA, https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

43. Because Edge sells oral vancomycin solution that is essentially a copy of FIRVANQ® and because FIRVANQ® is not on the drug shortage list, Edge is not in compliance with the requirements of section 503B. *See* 21 U.S.C. § 353b(a)(5).

44. Moreover, as noted above, section 503B limits the circumstances under which bulk drug substances may be used in compounding. An outsourcing facility may use a bulk drug substance in compounding only if it appears on a list to be developed by the FDA of bulk substances "for which there is a clinical need" or, alternatively, "the drug compounded from such

bulk drug substance" appears on the FDA's drug shortage list at the time of compounding, distribution, and dispensing. 21 U.S.C. § 353b(a)(2)(A).

45. The FDA has solicited nominations from the public for the "503B Bulks List," but has not yet initiated the notice-and-comment process mandated by the statute for establishing the formal list. *See* 78 Fed. Reg. 72838 (Dec. 4, 2013); 79 Fed. Reg. 37747 (July 2, 2014).

46. In June 2016, the FDA published industry guidance that was revised in January 2017 setting forth its interim regulatory policies for outsourcing facilities compounding using bulk drug substances. FDA, *Interim Policy on Compounding Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, (Jan. 2017) (the "2017 Interim Policy").[2]

47. Pursuant to the 2017 Interim Policy, drugs that have been nominated for placement on the 503B Bulks List are listed on the FDA's *Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, (last updated Oct. 31, 2019) (the "503B Nominated Bulk Drug List").[3]

48. The 2017 Interim Policy categorizes the bulk drug substances on the 503B Nominated Bulk Drug List into three categories:

a. Category 1 – substances nominated for the Bulks List that are currently under evaluation;

b. Category 2 – substances nominated for the Bulks List that raise significant safety risks; and

c. Category 3 – substances nominated for the Bulks List without adequate support.

[2] FDA, 2017 Interim Policy, https://www.fda.gov/media/94402/download.
[3] FDA, 503B Nominated Bulk Drug List, https://www.fda.gov/media/94164/download (last updated Oct. 31, 2019).

2017 Interim Policy at 5-6; *see generally* the 503B Nominated Bulk Drug List.

49. Pursuant to the 2017 Interim Policy, for drugs listed on the 503B Nominated Bulk Drug List under Category 1, the FDA's policy is to treat the drug as if "the bulk drug substance is ***not*** on the 503B bulks list." 2017 Interim Policy at 10 (emphasis added).

50. "Vancomycin hydrochloride" appears on the 503B Nominated Bulk Drug List as a Category 1 drug. 503B Nominated Bulk Drug List at 4. Therefore, pursuant to the FDA's 2017 Interim Policy, vancomycin is treated as not on the 503B Bulks List.

51. Because vancomycin is not on the 503B Bulks List and FIRVANQ® is not on the drug shortage list, Edge is not in compliance with 21 U.S.C. § 353b(a)(2)(A).

52. Because Defendant is in violation of section 503B's requirements at its purported 503B facility, the vancomycin produced at the Edge facility is not exempted from the drug-approval requirement.

53. Edge knows or should know that it is not complying with the requirements of section 503B. In 2015, the FDA issued Edge a Warning Letter advising it that the FDA had inspected Edge's facility and observed that Edge "failed to meet the conditions under section 503B of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain requirements under the FDCA." FDA Warning Letter, Ex. A at 1. The letter warned that Edge was "producing drugs that violate the FDCA." *Id.* at 2.

54. In particular, the FDA determined that Edge's facility did not comply with many of section 503B's requirements. The inspector observed that "some of [the Edge] facility's drug products [did] not include the following information on the label: a list of active and inactive ingredients, storage and handling instructions, and the statements, 'This is a compounded drug'

and 'Not for Resale.'" *Id.* at 2. The labels also omitted information "to facilitate adverse event reporting and a list of active and inactive ingredients . . . on the container." *Id.*

55. The letter also emphasized that Edge "failed to submit a report to FDA in June 2014, and again in December 2014, identifying the drug products that [it] compounded during the previous 6-month period." *Id.* The letter further warned that "failure to report drugs by an entity that is registered with the FDA in accordance with section 503B is a prohibited act" under the FDCA. *Id.* at 3.

56. The FDA also found that "drug products that were intended or expected to be sterile were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health, causing them to be adulterated" in violation of section 501(2)(A) of the FDCA. *Id.* at 2. The FDA observed violations of the current good manufacturing practice requirements regarding insanitary conditions.

57. As a result of the inspection and warning letter, Edge is aware that it must comply with section 503B requirements in order to qualify as an outsourcing facility.

58. As evidenced by the FDA's recent inspection report, Ex. B, however, Edge has not remedied its compliance failures. The FDA again inspected Edge's facility from February 15, 2018 to March 9, 2018, and then issued an FDA Form 483 Inspection report finding that Edge is not complying with section 503B's requirements. *Id.* In particular, the FDA highlighted that Edge's "drug products do not include information required by section 503B(a)(10)(A). *Id.*at 15. Notably, vancomycin was listed as an example of a drug whose label did not contain the required information. *Id.* at 16.

III. Edge's False and Misleading Advertising and Promotion.

59. Edge has made, and continues to make, false and misleading statements requiring its products in advertising and promotion.

60. Upon information and belief, Edge falsely and misleadingly represents to hospitals, physicians, and other health care providers that the drugs it manufactures and sells are lawfully "compounded" and exempt from drug-approval requirements.

61. Indeed, Edge's website contains several false or misleading statements, including:

a. "Edge Pharma is a pharmaceutical sterile and non-sterile 503B Outsourcing Facility offering high quality, innovative solutions for the health care community." EDGEpharma, Home Page, https://edgepharma.com (last visited February 11, 2020).

b. "As your compliance partner, we are dedicated to providing turnkey 503B outsourcing with the highest level of quality, easy ordering, simple logistics, and excellent customer support." *Id.*

c. "Edge Pharma is an FDA-registered and state-licensed, 503B Outsourcing Facility providing service to hospital pharmacies, outpatient surgery Centers, and clinics." *Id.*

d. "Our facility is compliant with the following state, local, and federal regulations and guidelines:

> USP 795, USP 797, USP 800
> Occupational Safety and Health Administration (OSHA)
> Food and Drug Administration (FDA)
> US Pharmacopeia (USP)
> Applicable Good Manufacturing Practice (GMP) Guidelines."

EDGEpharma, About Us, https://edgepharma.com/about-us/ (last visited February 11, 2020).

e. "Edge Pharma is a USP 797 and cGMP compliant FDA-Registered 503B Outsourcing Facility that specializes in a wide array of sterile and non-sterile

compounded medications." EDGEpharma, Products, https://edgepharma.com/products/ (last visited February 11, 2020).

f. "As an FDA registered and inspected 503B Outsourcing facility, Edge has the ability to react quickly to customer requirements and deliver cost effective solutions." EDGEpharma, Solutions, https://edgepharma.com/solutions/ (last visited February 11, 2020).

62. In addition to the misrepresentations on its website, upon information and belief, Edge distributes marketing and promotion materials to health care providers and consumers in which Edge falsely claims to be a "Registered and Inspected FDA Outsourcing Facility." *See* Exhibit C (examples of fax transmission to health care providers in Michigan).

63. As it is explained above, Edge is violating several conditions required for the section 503B outsourcing exemption to apply. Edge is not in compliance with section 503B, nor is it in compliance with FDA requirements. Accordingly, the above statements on Edge's website are false.

64. Such statements are materially misleading to health care providers and are intended to induce health care providers into believing that Edge complies with state and federal law, and that its products are safe, effective, and may lawfully be sold.

65. Health care providers and consumers reasonably rely on these statements in purchasing Edge's drugs. These representations have caused, and will continue to cause, health care providers and consumers to change their purchasing decisions and purchase Edge's drugs as opposed to drugs produced by other pharmacies or manufacturers, including Azurity. Neither health care providers nor consumers would purchase Edge's drugs if they knew that Edge is not 503B compliant and is unlawfully producing unapproved drugs.

66. Edge also makes false representations about vancomycin oral solution, stating that "commercially available options are not ideal for use in the hospital setting." EDGEpharma, Vancomycin Oral Solution, *supra* ¶ 32.

67. Azurity's FIRVANQ® is a commercially available vancomycin oral solution. Therefore, Edge's statement is false.

68. Health care providers and consumers reasonably rely on Edge's misrepresentation regarding vancomycin oral solution, as well as its many misrepresentations that it complies with 503B, in choosing to purchase Edge's vancomycin product instead of Azurity's drugs. Neither health care providers nor consumers would purchase Edge's vancomycin oral solution if they knew that Edge is not 503B compliant and is unlawfully producing unapproved drugs.

69. Edge's false and misleading statements were made in interstate commerce.

70. Azurity has suffered and will continue to suffer actual damages as a result of Edge's unfair competition.

IV. Demand Letter

71. On March 8, 2019, Azurity sent a cease and desist letter to Edge. *See* Exhibit D.

72. Azurity stated in the letter that FIRVANQ® is a commercially available, FDA-approved vancomycin hydrochloride oral solution, and that in producing an identical or near identical copy of the drug, Edge was in violation of section 503B. *Id.* at 1.

73. The letter further demanded that Edge cease its illegal production of vancomycin oral solution. *Id.*at 1.

74. On August 19, 2019, Azurity and Edge personnel, including William Chatoff, the Found and CEO of Edge, had a telephone conversation relating to the cease and desist letter during which Azurity emphasized its concern that Edge was and is engaged in illegal production of vancomycin.

75. Despite the cease and desist letter and the telephone conversation, Edge continues to market and produce vancomycin oral solution.

COUNT I

(Violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1))

76. Plaintiff repeats and realleges each allegation set forth herein.

77. Defendant's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a).

78. Defendant has violated the Lanham Act by using "false or misleading descriptions of fact" and "false or misleading representations of fact" in its commercial advertising or promotion that "misrepresent[] the nature, characteristics, [or] qualities" of its business practices and their products, as set forth above. These include (by way of example) its promotion of its business practices as lawful and its products as superior.

79. Defendant's false and misleading statements actually deceive and have the tendency to deceive a substantial segment of the intended audience.

80. The deception created from Defendant's false and misleading statements is material, in that it is likely to influence purchasing decisions of Azurity's current and prospective customers, as well as the purchasing decisions of other health care providers and consumers.

81. Defendant has caused its false and misleading statements to enter interstate commerce.

82. As a direct and proximate result of Defendant's conduct, Azurity has suffered and will continue to suffer injury in fact and actual damages resulting from Defendant's false and misleading advertising and promotion and unfair competitive practices, including the cost of corrective advertising needed to counter Defendant's false and misleading advertising.

83. Azurity seeks disgorgement of Defendant's profits and injunctive relief requiring Defendant to cease their false and misleading advertising and promotion and unfair competitive practices.

COUNT II

(Unfair and Deceptive Trade Practices Under Massachusetts General Laws Chapter 93A)

84. Plaintiff repeats and realleges each allegation set forth herein.

85. At all relevant times, the parties were acting in trade or commerce, as defined in the Massachusetts General Laws Chapter 93A.

86. Defendant's conduct constitutes one or more unfair and deceptive acts in violation of Chapter 93A and has resulted in harm to Plaintiff.

87. Defendant's conduct occurred primarily and substantially in the Commonwealth of Massachusetts.

88. Plaintiff has demanded that Defendant cease all such unfair and competitive tactics.

89. Defendant's wrongful conduct has been willful and intentional and will continue unless enjoined by the Court.

90. Because of Defendant's wrongful conduct, Plaintiff is suffering and will continue to suffer immediate and irreparable injury for which there is no adequate remedy at law unless Defendant is enjoined.

PRAYER FOR RELIEF

WHEREFORE, Azurity respectfully requests that this Court enter judgment in its favor:

1. A preliminary and permanent injunction enjoining Defendant from continuing the unlawful and unfair business practices alleged in this complaint;

2. A judgment that Defendant violated Section 43(a) of the Lanham Act;

3. A judgment that Defendant violated Chapter 93A of the Massachusetts General Laws;

4. Declaratory relief;

5. Damages and other compensatory relief;

6. Punitive damages to Plaintiff or Defendant's acts of unfair competition;

7. Multiple damages under Chapter 93A;

8. Attorneys' fees and costs injured in this action;

9. Prejudgment interest; and

10. Any further relief the Court may deem just and proper.

REQUEST FOR JURY TRIAL

Azurity demands a trial by jury on all claims and issues so triable.

Respectfully submitted,

/s/ Valerie C. Samuels

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